

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO

United States of America ex rel.
Jerry E. Hudson
751 Cascade Mills Drive
Akron, Ohio 44307

Plaintiff/Relator

v.

St. Jude Medical, Inc.
25777 Detroit Road, Suite 303
Westlake, Ohio 44145

Defendant/Respondent

and

Cleveland Clinic Foundation
9500 Euclid Avenue
Cleveland, OH 44195

Covenant Hospital Medical Center
700 Cooper Avenue
Saginaw, Michigan 48602

Elyria Memorial Hospital
630 East River Street
Elyria, OH 44035

Fairview Hospital
18101 Lorain Avenue
Cleveland, OH 44111

Hillcrest Hospital
6780 Mayfield Road
Mayfield Heights, OH 44124

JFK Medical Center
5301 South Congress Avenue,
Atlantis, FL 33462

Lakewood Hospital
14519 Detroit Avenue
Lakewood, Ohio 44107

CASE NO. 1:06CV2152

JUDGE POLSTER

MAG. JUDGE BAUGHMAN

FIRST AMENDED COMPLAINT FOR
VIOLATION OF FEDERAL FALSE
CLAIMS ACT [31 U.S.C. §3729 et seq.]
AND FOR MONEY DAMAGES

FILED IN CAMERA

UNDER SEAL

JURY TRIAL DEMANDED

Memorial Hospital)
1400 E Boulder Street)
Colorado Springs, CO 80909)
)
Parma Community General Hospital)
7007 Powers Boulevard)
Parma, OH 44129-5495)
)
Philadelphia Health & Education Corporation)
d/b/a Drexel University College of Medicine)
245 N. 15th Street)
Philadelphia, PA 19102)
)
Shands Hospital at the University of Florida)
801 SW 2nd Avenue)
Gainesville, FL 32601-6210)
)
St. Elizabeth's Health Center)
1044 Belmont Avenue)
Youngstown, Ohio 44501)
)
St John West Shore Hospital)
29000 Center Ridge Road)
Westlake, OH 44145)
)
St John Health - St John Detroit Riverview)
Hospital)
7733 East Jefferson Avenue)
Detroit, MI 48214)
)
St. Vincent Indianapolis Hospital)
2001 West 86th Street)
Indianapolis, Indiana 46260)
)
Thomas Jefferson University Medical College)
1020 Walnut Street)
Philadelphia, PA 19107-5587)
)
University Hospitals of Cleveland)
11100 Euclid Avenue)
Cleveland, OH 44106)
)
University of Kansas Medical Center)
3901 Rainbow Boulevard)
Kansas City, KS 66160)
)

York Hospital)
2250 East Market Street)
York, PA 17402)
)
William Beaumont Hospitals)
3601 W. Thirteen Mile Road,)
Royal Oak, Michigan 48073)
)
Respondents.)
)

Now comes Plaintiff/Relator, Jerry E. Hudson, by and through the undersigned counsel who brings this lawsuit against Defendant/Respondent St. Jude Medical, Inc. and Respondents Cleveland Clinic Foundation, Covenant Hospital Medical Center, Elyria Memorial Hospital, Fairview Hospital, Hillcrest Hospital, JFK Medical Center, Lakewood Hospital, Memorial Hospital, Parma Community General Hospital, Philadelphia Health & Education Corporation d/b/a Drexel University College of Medicine, St. Elizabeth's Health Center, St. John Westshore Hospital, St John Health - St John Detroit Riverview Hospital, St. Vincent Indianapolis Hospital, Shands Hospital at the University of Florida, Thomas Jefferson University Medical College, University Hospitals of Cleveland, University of Kansas Medical Center, William Beaumont Hospitals, and York Hospital, and for his Complaint states as follows:

INTRODUCTION

- 1) In this action, Plaintiff/Relator Hudson seeks to recover damages and civil penalties on behalf of the United States of America arising from violations of the Federal False Claims Act, 31 U.S.C. §3729 et seq., as amended ("the FCA" or "the Act") by Defendant/Respondent St. Jude Medical, Inc. ("St. Jude") and/or its agents, employees and co-conspirators, and by Respondents Cleveland Clinic Foundation ("CCF"), Covenant Hospital Medical Center ("Covenant"), Elyria Memorial Hospital ("EMH"), Fairview Hospital ("Fairview"), Hillcrest Hospital ("Hillcrest"), JFK Medical Center ("JFK"),

Lakewood Hospital ("Lakewood"), Memorial Hospital ("Memorial"), Parma Community General Hospital ("Parma"), Philadelphia Health & Education Corporation d/b/a Drexel University College of Medicine ("Drexel"), St. Elizabeth's Health Center ("St. Elizabeth's"), St. John Westshore Hospital ("St. John Westshore"), St John Health - St John Detroit Riverview Hospital ("St. John"), St. Vincent Indianapolis Hospital ("St. Vincent"), Shands Hospital at the University of Florida ("Shands"), Thomas Jefferson University Medical College ("Thomas Jefferson"), University Hospitals of Cleveland ("UH"), University of Kansas Medical Center ("UKMC"), William Beaumont Hospitals ("Beaumont"), and York Hospital ("York") (collectively referred to herein as "the Respondent Hospitals"). The conduct and false claims at issue here were carried out St. Jude and the Respondent Hospitals in connection with the manufacture, distribution and sale of cardiac monitoring equipment, cardiac defibrillators, cardiac stents and other medical devices. Additionally, this is an action under Ohio law to recover damages against St. Jude for age discrimination, wrongful discharge and breach of implied contract.

THE FALSE CLAIMS ACT

- 2) The Act was originally enacted during the Civil War, and was amended in 1986. Congress amended the Act to enhance the Government's ability to recover losses sustained as a result of fraud against the United States after finding that fraud in federal programs was pervasive and that the Act, which Congress characterized as the primary tool for combating government fraud, was in need of modernization. Congress intended that the amendments create incentives for individuals with knowledge of fraud against the government to disclose the information without fear of reprisals or Government inaction, and to encourage the private bar to commit legal resources on the Government's behalf.

- 3) The Act provides that any person who knowingly submits, or causes the submission of, a false or fraudulent claim to the U.S. Government for payment or approval is liable for a civil penalty for each such claim, plus three times the amount of the damages sustained. Liability attaches when a party knowingly makes, uses, or causes to be made or used false records and statements, and omitted material facts, to obtain Government payment for false and fraudulent claims.
- 4) The Act allows any person having information about a false or fraudulent claim against the federal government to bring an action for himself or herself and the government, and to share in any recoveries. The Act requires that the complaint be filed under seal for a minimum of 60 days (without service on the Defendants and/or Respondents during that time) to allow the Government time to conduct its own investigation and to determine whether to join the suit.
- 5) Based on these provisions, *qui tam* Plaintiff/Relator Jerry Hudson seeks through this action to recover damages and civil penalties arising from practices in which St. Jude and the Respondent Hospitals made or caused to be made false or fraudulent records, statements and directly and/or indirectly, to obtain payment for products sold to the United States Government.

PARTIES AND JURISDICTION

- 6) Plaintiff/Relator Jerry E. Hudson ("Plaintiff/Relator" or "Mr. Hudson") is a resident of Akron, Ohio and served as a Regional Sales Manager for the U.S. Sales Division of St. Jude Medical S.C., Inc. from February 6, 2004 until his termination on September 9, 2005.
- 7) St. Jude is a Minnesota Corporation with its corporate offices in Woodland Hills, California. St. Jude maintains a regional sales division office in the City of Westlake, County of Cuyahoga, Ohio.

- 8) CCF is a hospital that provides medical services for which reimbursement may be sought under the Medicare and/or state health care programs. CCF's principal place of business is located in County of Cuyahoga, Ohio.
- 9) Covenant is a hospital that provides medical services for which reimbursement may be sought under Medicare and/or state health care programs. Covenant's principal place of business is located in Saginaw, Michigan.
- 10) Elyria is a hospital that provides medical services for which reimbursement may be sought under Medicare and/or state health care programs. Elyria's principal place of business is located in Lorain County, Ohio.
- 11) Fairview is a subsidiary of CCF and is a hospital that provides medical services for which reimbursement may be sought under the Medicare and/or state health care programs. Fairview's principal place of business is located in County of Cuyahoga, Ohio.
- 12) Hillcrest is a subsidiary of CCF and is a hospital that provides medical services for which reimbursement may be sought under Medicare and/or state health care programs. Hillcrest's principal place of business is located in County of Cuyahoga, Ohio.
- 13) JFK is a hospital that provides medical services for which reimbursement may be sought under Medicare and/or state health care programs. JFK's principal place of business is located in Atlantis, Florida.
- 14) Lakewood is a subsidiary of CCF and is a hospital that provides medical services for which reimbursement may be sought under Medicare and/or state health care programs. Lakewood's principal place of business is located in County of Cuyahoga, Ohio.

- 15) Memorial is a hospital that provides medical services for which reimbursement may be sought under Medicare and/or state health care programs. Memorial's principal place of business is located in Colorado Springs, CO.
- 16) Parma is a hospital that provides medical services for which reimbursement may be sought under Medicare and/or state health care programs. Parma's principal place of business is located in Cuyahoga County, Ohio.
- 17) Drexel is a hospital that provides medical services for which reimbursement may be sought under Medicare and/or state health care programs. Drexel's principal place of business is located in Philadelphia, Pennsylvania.
- 18) St. John Westshore is a hospital that provides medical services for which reimbursement may be sought under Medicare and/or state health care programs. On information and belief, St. John Westshore is a subsidiary of UH with its principal place of business is located in Cuyahoga County, Ohio.
- 19) St. Elizabeth's is a hospital that provides medical services for which reimbursement may be sought under Medicare and/or state health care programs. St. Elizabeth's principal place of business is located in Youngstown, Ohio.
- 20) St. John is a hospital that provides medical services for which reimbursement may be sought under Medicare and/or state health care programs. St. John's principal place of business is located in Detroit, Michigan.
- 21) St. Vincent is a hospital that provides medical services for which reimbursement may be sought under Medicare and/or state health care programs. St. Vincent's principal place of business is located in Indianapolis, IN.

- 22) Shands is a hospital that provides medical services for which reimbursement may be sought under Medicare and/or state health care programs. Shand's principal place of business is located in Gainesville, Florida.
- 23) Thomas Jefferson is a hospital that provides medical services for which reimbursement may be sought under Medicare and/or state health care programs. Thomas Jefferson's principal place of business is located in Philadelphia, Pennsylvania.
- 24) UH is a hospital that provides medical services for which reimbursement may be sought under Medicare and/or state health care programs. UH's principal place of business is located in Cuyahoga County, Ohio.
- 25) UKMC is a hospital that provides medical services for which reimbursement may be sought under Medicare and/or state health care programs. UKMC's principal place of business is located in Kansas City, Kansas.
- 26) Beaumont is a hospital that provides medical services for which reimbursement may be sought under Medicare and/or state health care programs. Beaumont's principal place of business is located in Detroit, Michigan.
- 27) York is a hospital that provides medical services for which reimbursement may be sought under Medicare and/or state health care programs. York's principal place of business is located in York, Pennsylvania.
- 28) The Office of Personnel Management ("OPM") is an agency of the United States responsible for, among other things, administering the Federal Employees Health Benefits Plan ("FEHBP"). FEHBP is a program through which the federal Government provides health insurance to more than 10 million people, including current federal employees, their dependents, retired federal employees, and the dependents of retirees

- 29) The United States Department of Health and Human Services ("HHS"), acting by and through the Health Care Financing Administration ("HCFA"), is an agency of the United States responsible for, among other things, administering the Medicare and Medicaid health insurance programs.
- 30) The Office of Civilian Health and Medical Program of the Uniformed Services is an agency of the United States which administers the Civilian Health and Medical Program of the Uniformed Services ("CHAMPUS"). CHAMPUS funds a substantial portion of the health care that civilian hospitals, physicians and other providers furnish to military retirees, the dependents of military retirees, and the dependents of active-duty personnel and deceased military members. The funds used by CHAMPUS are appropriated by Congress through the annual appropriation acts for the Department of Defense and HHS.
- 31) The Department of Veterans Affairs ("VA"), is an agency of the United States responsible for, among other things, entering into and administering contracts for the procurement of medical devices to be used at hospitals and other facilities owned and operated by the VA and the United States Department of Defense.
- 32) This Court has jurisdiction over the subject matter of this action pursuant to both 28 U.S.C. §1331 and 31 U.S.C. §3732, the latter of which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§ 3729 and 3730.
- 33) This Court has personal jurisdiction over St. Jude and the Respondent Hospitals pursuant to 31 U.S.C. §3732(a) because that section authorizes nationwide service of process and because St. Jude and the Respondent Hospitals have minimum contacts with the United States. Moreover, St. Jude and several of the Respondent Hospitals can be found in, reside or transact or have transacted business in the Northern District of Ohio. Venue is proper in this

District pursuant to 31 U.S.C. §3732(a) because St. Jude and several of the Respondent Hospitals can be found in and transactor have transacted business in the Northern District of Ohio. In addition, statutory violations alleged in this Complaint occurred in this district.

34) Plaintiff/Relator also brings state law employment discrimination and common law claims over which this Court has supplemental subject matter jurisdiction under 28 U.S.C. § 1367.

FACTUAL BACKGROUND

35) Mr. Hudson entered into a written employment agreement with St. Jude on February 6, 2004, pursuant to which he would serve as a Regional Sales Manager in St. Jude's Northeast Ohio region.

36) As a regional sales manager, Mr. Hudson was responsible for, among other things, overseeing district sales representatives, ensuring their compliance with company and industry standards, and providing support to employees responsible for sales of medical devices.

37) Mr. Hudson's efforts as a regional sales manager for St. Jude enabled his sales region to increase its productivity from below plan achievement to above plan achievement in 2005 and in less than one year's time.

38) During the course of his employment with St. Jude, Mr. Hudson took efforts to ensure that his sales representatives complied with the industry standards set forth in the Code of Ethics On Interactions With Health Care Professionals and adopted by The Advanced Medical Technology Association, the guidelines adopted by the Office of Inspector General of the Department of Health and Human Services, and the federal anti-kickback statute codified in 42 U.S.C. 1320a-7b(b), each of which prohibits improper inducements or other remuneration to promote sales.

- 39) Mr. Hudson verbally questioned various offers made to customers of St. Jude and objected to practices of St. Jude representatives when he believed applicable standards, guidelines and statutory obligations were not being followed.
- 40) During the course of Mr. Hudson's employment with St. Jude, Mr. Hudson observed efforts by St. Jude to use research incentives to regain access to previously lost business accounts, to persuade physicians to use St. Jude's products, and to increase market share.
- 41) In an effort to regain business from the Veterans Administration Medical Center, for example, St. Jude encouraged its sales representatives to offer its physicians various clinical studies and/or provide cardiac resynchronization therapy devices to its physicians without a formal waiver process. (St. Jude's efforts in this regard are evidenced in the e-mail correspondence attached hereto as Exhibit A.)
- 42) St. Jude also used clinical studies to persuade physicians at various hospitals to use up, or "burn off," products sold in bulk quantity purchases to hospitals which remained on the shelf toward the end of the sales quarter. By way of illustration, and not limitation, in 2005 St. Jude attempted to offer various clinical studies to physicians at hospitals in the Cleveland Clinic health system, including CCF, Fairview, Lakewood, and Hillcrest, and at UH in an effort to persuade them to use up previously purchased St. Jude products. (See February 10, 2005 Email correspondence attached hereto as Exhibit B.) St. Jude also offered an Endocardial Solutions Inc. ("ESI") mapping system to physicians in an effort to persuade hospitals to increase the purchase of St. Jude's medical devices. For example, St. Jude attempted to place research equipment at UH for use by a physician in exchange for a commitment from the physician to increase purchases of St. Jude's pacemakers and implantable cardioverter defibrillators ("ICD's"). In doing so, St. Jude also attempted to, and

did, obtain a commitment from the UH physician to influence purchases made by another hospital system. (See April 8, 2005 E-mail correspondence attached hereto as Exhibit C.) In fact, St. Jude benefited from a \$900,000.00 quantity purchase of these devices in exchange for the placement of the research equipment.

43) Later in 2005, St. Jude offered, and Beaumont, agreed to a leveraged agreement to purchase St. Jude devices in action for the opportunity to acquire an Epicor system without any capital dollars. (See July 6, 2005 Email correspondence attached hereto as Exhibit N.)

44) Similarly, in an effort to increase sales of its cardiac rhythm management ("CRM") devices to the CCF, St. Jude offered to provide the CCF with an ESI system if the physicians at CCF would agree to "drive increased CRM units" despite concerns from the physicians that such efforts would be prohibited by CCF's legal department. (See Exhibit B.) St. Jude's efforts paid off, and in 2005, with St. Jude's influence, CCF's physicians committed to implanting one St. Jude ICD each day with a total of "5 ICD's per week or 2 CRT's [cardiac resynchronization therapy device] and 3 to 4 ICD's per week as need to help with the acquisition of the ESI/St. Jude System." (See March 4, 2005 Email correspondence attached hereto as Exhibit D.) St. Jude also offered similar incentives to other hospitals in Ohio such as St. John Westshore and affiliates of the CCF, including Fairview, Lakewood, and Hillcrest.

45) In 2005, St. Jude directed sales representatives to explore leverage opportunities with the ESI system to increase sales of its CRM and electrophysiology ("EP") devices. If St. Jude's customers refused to commit to CRM and EP sales, customers were to be advised that the ESI systems would be removed from their facilities. (See Exhibit E, Email correspondence dated March 2, 2005 and the document attached thereto.)

- 46) On information and belief, Hillcrest, JFK, UKMC, Shands, York and Memorial agreed to commit to CRM and EP sales in exchange for the continued placement of the ESI system.
- 47) St. Jude was fully aware of the impropriety of conditioning research initiatives on sales of its products. As a result, St. Jude's policy was to preclude employees from making reference to clinical study activities in e-mail communications and monthly reports. (See E-mail correspondence dated August 12, 2005 attached hereto as Exhibit F.)
- 48) In addition to clinical study and research inducements, St. Jude also offered hospitals and physicians incentives in the form of rebate dollars to induce future purchases. For instance in 2004, St. Jude proposed a "rapid rebate" program to the CCF. Pursuant to the terms of the proposal (as described in the August 26, 2004 Email correspondence attached as Exhibit G), if CCF agreed to purchase a minimum quantity of St. Jude's devices, the CCF would receive an initial 3% rebate on products which were purchased in the prior quarter and an additional rebate on the same products if implanted in the current quarter. That same year, St. Jude offered Parma a similar rapid rebate proposal, pursuant to which the hospital would receive a rebate of \$400 per ICD on the hospital's entire quantity purchase if the items were implanted within 60 days of receipt and a commitment for another quantity purchase order was placed prior to the end of the same quarter. (See June 9, 2004 Proposal attached hereto as Exhibit H.) This companywide practice had the effect of inflating St. Jude's performance within a sales quarter.
- 49) St. Jude also encouraged physicians in hospitals to increase support for purchases of St. Jude cardiac rhythm management devices in exchange for continued rebates on quantity purchases of those items. In fact, St. Jude employed a systematic strategy of offering research incentives and rebates to various hospitals in exchange for commitments to purchase

quantities of St. Jude's CRM devices. By way of illustration, and not limitation, in an effort to increase purchases from the CCF, alone, St. Jude's January 2005 incentives (in the form of research and rebates) to the CCF totaled \$186,000.00. (See E-mail correspondence dated February 10, 2005 attached hereto as Exhibit I.)

50) In 2005, St. Jude also offered rebates payable to EMH's EP/Cardiology department for educational purposes based upon EMH's commitment to purchase bulk quantities of St. Jude devices. (See EMH 2005 Proposal attached hereto as Exhibit M.)

51) St. Jude also engaged in systematic practice of offering back-end rebates on previously purchased products and/or used if customers would commit to larger quantity purchases at the end of a quarter. For instance, in March 2005, St. Jude provided University Hospitals of Cleveland with back-end rebates totaling \$14,475.00 for purchases made in third quarter of 2004 once it received a commitment to a larger than normal quantity purchase at the end of the first quarter in 2005. (See Email correspondence dated March 15, 2005 attached hereto as Exhibit J.)

52) In March of 2005, St. Jude also offered Fairview the opportunity to receive funding for its EP educational fund in the form of rebates on "burn-off's" of previously purchased products. (See Email correspondence dated March 15, 2005 attached hereto as Exhibit O.)

53) St. Jude, as a matter of company policy, required its sales representatives to subsidize clinical studies which were offered to various hospitals as inducements. These subsidies were effected through commission reductions. An example of St. Jude's commission reduction agreement is attached hereto as Exhibit K.

54) In addition to the research and rebate incentives offered by St. Jude, physicians throughout Ohio, Michigan and Indiana, that committed to using St. Jude's medical devices were also

provided with “consulting” opportunities, wherein the physicians agreed to advise and consult with St. Jude and would permit representatives from St. Jude to observe implants of St. Jude’s devices in exchange for direct monetary payments. The Memorandum attached hereto as Exhibit L provides a summary of the initiatives to obtain consulting arrangements as well as a listing of the hospitals, including but not limited to St. John, Covenant, St. Vincent, EMH, and UH, where physicians with pending consulting arrangements are located.

55) In April 2005, for instance, Dr. Bruce Stambler of UH received payment from St. Jude for “consulting” opportunities with regard to the implantation of CRT devices on January 14 and 25, 2005, February 3, 2005 in patients Jane Doe 1 and John Does 1 and 2. (See E-mail correspondence dated April 26, 2005 attached hereto as Exhibit P.)

56) In addition to rebate, research, and “consulting” opportunities, St. Jude had a corporate policy to exchange grant and charitable support for increased usage of its products. For example, in 2005, St. Jude offered Drexel a \$100,000 donation for its Congestive Heart Failure program in exchange for purchase of St. Jude cardiac devices. See January 25, 2005 and January 10, 2006 emails attached hereto as Exhibits Q.

57) In 2005 and 2006, St. Jude offered Jefferson grant support of educational programs in exchange for increased implantation of St. Jude cardiac devices. See January 2006 emails attached hereto as Exhibit R.

58) Improper inducements and incentives were not limited to Mr. Hudson’s region but were company-wide policy as shown by Exhibit E, the attachment thereto, and Exhibit K in violation of the Federal Medicare and Medicaid anti-kickback statute.¹

¹ 42 U.S.C. § 1320a-7b(b), Illegal remunerations. The anti-kickback statute provides in pertinent part as follows:

- 59) Further, upon information and belief, St. Jude's company wide policy is to provide grants in exchange for increased utilization of St. Jude products. The grant program is a nationwide and company wide program as evidenced by Exhibits S and T. This linkage is further verified in that the grant requests are being made by St. Jude sales representatives.
- 60) For his part, Mr. Hudson entered into a written employment agreement with St. Jude on February 6, 2004, pursuant to which he would serve as a Regional Sales Manager in St. Jude's Northeast Ohio region.
- 61) As a regional sales manager, Mr. Hudson was responsible for, among other things, overseeing district sales representatives, ensuring their compliance with company and industry standards, and providing support to employees responsible for sales of medical devices.
- 62) During the course of his employment with St. Jude, Mr. Hudson took efforts to ensure that his sales representatives complied with the industry standards set forth in the Code of Ethics On Interactions With Health Care Professionals and adopted by The Advanced Medical Technology Association, the guidelines adopted by the Office of Inspector General of the Department of Health and Human Services, and the federal anti-kickback statute codified in 42 U.S.C. 1320a-7b(b), each of which prohibits improper inducements or other remuneration to promote sales.

“(2) whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—

(A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a federal health care program, or

(B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a federal health care program,
shall be guilty of a felony . . .” (Emphasis added).

- 63) Mr. Hudson verbally questioned various offers made to customers of St. Jude and objected to practices of St. Jude representatives when he believed applicable standards, guidelines and statutory obligations were not being followed.
- 64) As a result of Mr. Hudson's practice of questioning and/or challenging conduct that failed to comply with the industry standards, federal guidelines and federal statutes identified above, Mr. Hudson was systematically excluded from sales meetings with customers, and he suffered a lack of managerial support from his supervisor.
- 65) On August 12, 2005, Michael Moore ("Mr. Moore"), Vice President for the North Mid-West Region of St. Jude's U.S. Sales Division and Mr. Hudson's supervisor, met with Mr. Hudson to address, for the first time, Mr. Moore's supposed concerns about Mr. Hudson's management performance.
- 66) Then, on September 9, 2005, contrary to St. Jude's policy of providing employees with an opportunity to improve performance, Mr. Moore, Mr. Hudson's supervisor, terminated Mr. Hudson. Mr. Moore refused to provide a reason for the employment action and, instead, Mr. Moore simply complained of a vague performance issue which he had never previously addressed with Mr. Hudson.
- 67) Federal anti-kickback law prohibits individuals and entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration in order to induce business reimbursed under the Medicare or state health care programs. The types of remuneration covered specifically include kickbacks, bribes, and rebates, whether made directly or indirectly, overtly or covertly, in cash or in kind. Prohibited conduct includes remuneration intended to induce referrals of patients and remuneration intended to induce the purchasing,

leasing, ordering, or arranging for any good, facility, service or item paid for by Medicare or state health care programs.

68) As a result of St. Jude's fraudulent practices and inducements in connection with the manufacture, distribution and sale of cardiac monitoring equipment, cardiac defibrillators, cardiac stents and other medical devices, claims for payment in connection with such sales were rendered false or fraudulent.

69) To conceal its improper practices, St. Jude made or caused to be made false and/or fraudulent records, statements and omissions. Such false and/or fraudulent records, statements and omissions were made, directly and/or indirectly, to obtain payment for cardiac monitoring equipment, cardiac defibrillators, cardiac stents and other medical devices products sold to the United States Government.

70) St. Jude also caused private health care providers, including the Respondent Hospitals, to submit false and/or fraudulent claims for reimbursement of certain capital expenses incident to patient care, including patient diagnostic and monitoring equipment. St. Jude caused the Respondent Hospitals to prepare false and/or fraudulent records and statements in order to obtain reimbursement from the Office of Personnel Management, Medicare, Medicaid, CHAMPUS, Veterans Administration and other federal-funded health insurance programs. In particular, the Respondent Hospitals were caused to improperly include the cost of medical devices as capital costs on cost reports submitted in connection with federal health insurance programs. As a result, the federal government was caused to pay inflated reimbursements for cardiac products.

71) As providers whose services may have been subject to reimbursement from Medicare or State health programs, the Respondent Hospitals were required to enter into a provider

agreement with the United States Government, pursuant to which they certified that they would comply with all laws and regulations concerning proper practices for Medicare providers, including but not limited to the Federal Medicare and Medicaid anti-kickback statute.

72) Compliance with the Medicare provider agreement is a condition for the receipt of payments from the Medicare program.

73) In receiving and accepting the unlawful inducements and benefits offered by St. Jude, the Respondent Hospitals failed to comply with the requirements of the Medicare provider agreements. Nevertheless, the Respondent Hospitals submitted cost reports to the United States Government certifying their compliance with federal health care laws know those certifications were false.

COUNT ONE
(Violations of False Claims Act 31 U.S.C. §3729(a)(1), (2), and (7))

74) Plaintiff/Relator restates, reasserts and re-alleges the foregoing statements, assertions and allegations as if fully rewritten herein.

75) This is a claim for treble damages and forfeitures under the False Claims Act, 31 U.S.C. §3729, et seq., as amended.

76) By virtue of the acts described above, St. Jude and the Respondent Hospitals knowingly presented, or caused to be presented, false or fraudulent claims for payment to the United States Government, and knowingly failed to disclose material facts, in order to obtain Government payment.

77) By virtue of the acts described above, St. Jude and the Respondent Hospitals knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to obtain Government payment for false and fraudulent claims.

78) By virtue of the acts described above, St. Jude and the Respondent Hospitals knowingly made, used, or caused to be made or used false records to conceal, avoid, or decrease an obligation to pay or transmit money to the Federal Government.

79) By reason of these payments, the United States has been damaged, and continues to be damaged, in substantial amount.

COUNT TWO
False Claims Act 31 U.S.C. §3730(h)

80) Plaintiff/Relator restates, reasserts and re-alleges the foregoing statements, assertions and allegations as if fully rewritten herein.

81) This is a claim for reinstatement, two times the amount of back pay, interest on the back pay, and special damages for retaliatory discharge as provided by the False Claims Act, 31 U.S.C. §3730(h).

82) By virtue of the acts described above, St. Jude discharged Plaintiff/Relator because of lawful acts done in furtherance of an action under 31 U.S.C. §3729 et seq.

83) By reason of this wrongful discharge, St. Jude is liable to Plaintiff/Relator.

COUNT THREE
(Wrongful Discharge)

84) Plaintiff/Relator restates, reasserts and re-alleges the foregoing statements, assertions and allegations as if fully rewritten herein.

85) Pursuant to the Code of Ethics On Interactions With Health Care Professionals adopted by The Advanced Medical Technology Association (“Code of Ethics”), the guidelines adopted by the Office of Inspector General of the Department of Health and Human Services (“OIG Guidelines”), and the federal anti-kickback statute codified in 42 U.S.C. 1320a-7b(b), manufacturers in the medical device industry have a duty to ensure that their sales

representatives engage in ethical business practices and refrain from improper and unlawful of marketing and promotion of products.

86) Further, sales representatives in the medical device industry are bound by ethical codes and federal statutes and guidelines to engage in ethical business practices and to refrain from improper and unlawful of marketing and promotion of products.

87) Mr. Hudson was retaliated against and terminated by Moore and St. Jude in violation of express public policies embodied in the Code of Ethics, the OIG Guidelines, and the federal anti-kickback statute.

88) St. Jude lacked a legitimate business justification for Mr. Hudson's termination.

89) As a direct and proximate result of St. Jude's retaliation and wrongful discharge of Plaintiff/Relator in violation of public policy, Plaintiff/Relator has suffered lost wages, loss of future wages, damage to his reputation, and emotional pain and suffering.

90) St. Jude's conduct was outrageous, reckless, willful and oppressive and in complete disregard of Plaintiff/Relator's rights.

COUNT FOUR
(Breach of Implied Contract)

91) Plaintiff/Relator restates, reasserts and re-alleges the foregoing statements, assertions and allegations as if fully rewritten herein.

92) St. Jude had a corporate policy of providing employees with an opportunity to improve performance when a manager or supervisor determined that an employee's performance was below a satisfactory level.

93) Mr. Hudson reasonably and justifiably believed that, in the event his performance was determined to be below a satisfactory level, he would be given an opportunity to improve his

performance prior to facing any disciplinary action, including but not limited to termination of his employment.

94) Although Mr. Hudson was confronted with alleged performance issues on August 12, 2005, he was not permitted an opportunity to improve his performance. Instead, St. Jude terminated his employment.

95) Mr. Hudson justifiably relied upon St. Jude's promises and assurances.

96) As a result of St. Jude's breach, Mr. Hudson has suffered damages for which St. Jude is liable.

WHEREFORE, Plaintiff/Relator Jerry E. Hudson prays for judgment in his favor and against Defendant/Respondent St. Jude Medical, Inc. and Respondents Cleveland Clinic Foundation, Covenant Hospital Medical Center, Elyria Memorial Hospital, Fairview Hospital, Hillcrest Hospital, JFK Medical Center, Lakewood Hospital, Memorial Hospital, Parma Community General Hospital, Philadelphia Health & Education Corporation d/b/a Drexel University College of Medicine, St. Elizabeth's Health Center, St. John Westshore Hospital, St John Health - St John Detroit Riverview Hospital, St. Vincent Indianapolis Hospital, Shands Hospital at the University of Florida, Thomas Jefferson University Medical College, University Hospitals of Cleveland, University of Kansas Medical Center, William Beaumont Hospitals, and York Hospital as follows:

- (a) On Count One, 1) that Defendant/Respondent and the Respondent Hospitals cease and desist from violating 31 U.S.C. §3729; 2) That this Court enter judgment against Defendant/Respondent and the Respondent Hospitals in an amount equal to three times the amount of damages the United States has sustained because of the actions of Defendant/Respondent and the Respondent Hospitals, plus a civil

penalty of not less than \$5,500 and not more than \$11,000 for each violation of 31 U.S.C. §3729; 3) that Plaintiff/Relator be awarded the maximum amount allowed pursuant to §3730(d) of the False Claims Act;

- (b) On Count Two, 1) that Plaintiff/Relator recover two times his back pay, plus interest, lost as a result of defendant's retaliatory discharge; 2) that Plaintiff/Relator be reinstated; and 3) that Plaintiff/Relator recover special damages suffered as a result of Defendant/Respondent St. Jude's retaliatory discharge.
- (c) On Count Three, for compensatory damages arising from Plaintiff/Relator's wrongful termination in violation of public policy in an amount not less than Twenty-Five Thousand Dollars (\$25,000.00), plus punitive damages in an amount to be determined at trial and interest thereon,
- (d) On Count Four, for damages arising from Defendant/Respondent St. Jude's breach of its promises to Plaintiff/Relator in an amount not less than Twenty-Five Thousand Dollars (\$25,000.00) together with interest thereon,
- (e) For attorneys fees, costs and disbursements of this action, and
- (f) For such other and further relief as this Court may deem just and proper.

Respectfully submitted,


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*One of the Attorneys for Plaintiff/Relator Jerry E.
Hudson*

JURY DEMAND

Plaintiff/Relators hereby demand a trial by Jury pursuant to R. 38 of the Federal Rules of
Civil Procedure.

Warner Merdenhall/aml
One of the Attorneys for Plaintiff/Relator

CERTIFICATE OF SERVICE

A true and accurate copy of the foregoing was served via e-mail and United States regular mail this 12th day of March 2007 upon the following

Alex Rokakis, Esq.
Assistant U.A. Attorney
801 West Superior Avenue, Suite 400
Cleveland, Ohio 44113



One of the attorneys for Plaintiff/Relator
Jerry E. Hudson